SECTION 1

INTRODUCTION

1.1 OVERVIEW AND OBJECTIVES

Toxic chemicals released to the environment from point sources such as industrial and municipal discharges and from nonpoint sources such as agricultural runoff and atmospheric deposition have contaminated surface waters and their sediments across the United States. In some areas, contamination arises from one or more related chemicals. For example, in the Hudson River in New York, attention has focused on high concentrations of a group of related chemicals called polychlorinated biphenyls, or PCBs. In other areas, a complex mixture of chemicals is present. For example, over 900 different synthetic organic compounds have been found in Puget Sound in Washington State, while nearly 1,000 chemical contaminants have reportedly been found in the Great Lakes.

Many chemical pollutants concentrate in fish and shellfish by accumulating in fatty tissues or selectively binding to fish muscle tissue (the fillet). Even extremely low concentrations of bioaccumulative pollutants detected in water or bottom sediments may result in fish or shellfish tissue concentrations high enough to pose health risks to fish consumers. Lipophilic contaminants, particularly certain organochlorine compounds, tend to accumulate in the fatty tissues of fish. Consequently, fish species with a higher fat content, such as carp, bluefish, some species of salmon, and catfish, may pose greater risks from some contaminants than leaner fish such as bass, sunfish, and yellow perch. Although exposure to some contaminants may be reduced by removing the fat, skin, and viscera before eating, other contaminants, such as methylmercury, accumulate in the muscle tissue of the fillet, and therefore cannot be removed by trimming. In addition, some fish are consumed whole or are used whole in the preparation of fish stock for soups and other foods. Under these conditions, the entire body burden of bioaccumulative contaminants contained in the fish would be ingested by the consumer (U.S. EPA, 1991b).

In addition to the risks borne by the general population due to consumption of contaminated fish, various populations eating higher-than-average quantities of fish are at greater risk of having higher body burdens of bioaccumulative contaminants. Those at greatest risk include sport and subsistence fishers. In this document, subsistence fishers are defined as fishers who rely on noncommercially caught fish and shellfish as a major source of protein in their diets. Within these “at-risk” populations, pregnant women and children may be at even greater risk of

incurring adverse effects than other members of the populations, due to their proportionally higher consumption rates and/or increased susceptibility to adverse toxicological effects.

Fish contaminants vary widely in chemical structure and toxic properties. Potential adverse health effects include cancer, chronic systemic effects, and developmental and reproductive effects to name a few. The severity of these effects varies with the exposure level and characteristics of the individual and may range from relatively mild disease states to premature death. Recently attention has focused on the developmental effects of chemical contaminants because studies conducted over the past two decades have identified many environmental pollutants as causing developmental abnormalities and other adverse reproductive outcomes. For example, in developing a protocol for uniform sport fish consumption advisories across the Great Lakes, the Great Lakes Sport Fish Advisory Task Force used developmental and reproductive toxicity endpoints in calculating their recommended consumption limits.

State, local, and Federal agencies and Tribal organizations currently use a range of methods to estimate risks to human health from consumption of chemically contaminated fish. Results of a 1989 survey of such methods (Cunningham et al.,1990), funded by the U.S. Environmental Protection Agency (EPA) and conducted by the American Fisheries Society, identified the need for standardizing the approaches to assessing risks and for developing advisories for contaminated fish and shellfish. Four key components were identified as critical to the development of a consistent risk-based approach to developing consumption advisories: standard practices for sampling and analyzing fish and shellfish, standardized risk assessment methods, standardized procedures for making risk management decisions, and standardized approaches to risk communication.

Note: Throughout this document series, the term "fish" refers to sport- and subsistence-caught freshwater, estuarine, and marine fish and shellfish, unless otherwise noted.

To address concerns raised by the survey, EPA developed a series of four documents designed to provide guidance to State, local, Regional, and Tribal environmental health officials who are responsible for issuing fish consumption advisories for noncommercially caught fish. The documents are meant to provide guidance only and do not constitute a regulatory requirement. The documents are: *Guidance for Assessing Chemical Contamination Data for Use in Fish Advisories, Volume 1: Fish Sampling and Analysis* (released 1993 and revised in 1995), *Volume 2: Risk Assessment and Fish Consumption Limits* (first released in 1994), *Volume 3: Risk Management* (released in 1996), *and Volume 4: Risk Communication* (released in 1995). EPA recommends that the four volumes of this guidance series be used together, since no one volume provides all the necessary information to make decisions regarding the issuance of fish consumption advisories.

This volume (Volume 2) provides guidance on risk assessment procedures to use in the development of risk-based consumption limits for the 25 high-priority chemical contaminants identified in Volume 1. The target analytes listed in Table 1-1 were selected by EPA's Office of Water as particularly significant fish contaminants, based on their occurrence in fish and shellfish (as evidenced by their detection in regional or national fish monitoring programs or by State issuance of a fish advisory), their persistence in the environment (half-life >30 days), their potential for bioaccumulation (BCF values >300), and their oral toxicity to humans. The criteria for their selection are discussed in Volume 1, Section 4, of this series. This second edition of Volume 2 makes refinements to the first edition including major organizational changes in the presentation of the discussion of risk assessment procedures and other information—inclusion of new information formerly found in supplemental documents, the addition of revised toxicological summary data on methylmercury and PCBs, and new toxicological data on arsenic, polyaromatic hydrocarbons (PAHs), and tributyltin.

1.2 CONTENTS OF VOLUME 2

Figure 1-1 shows how Volume 2 fits into the overall guidance series and lists the major categories of information provided. This volume covers topics necessary for conducting risk assessments related to consumption of chemically contaminated fish. The first four sections follow the anticipated sequence of activities to conduct a risk assessment, develop risk-based consumption limits, and prepare consumption limit tables for a range of fish contaminant levels, meal sizes, and consumers. The last two sections provide summary information on the toxicology properties of the 25 target analytes and geographic information system (GIS) mapping tools for risk assessment and risk management.

Section 1 of this document reviews the development of this guidance document series, lists the 25 target analytes of concern with respect to chemical contamination of fish and shellfish, summarizes additions and revisions to this second edition, and references information used in the development of this document.

Section 2 introduces the EPA four-step risk assessment process: hazard identification, dose-response assessment, exposure assessment, and risk characterization. Details on each of these steps are provided, along with a discussion of the major uncertainties and assumptions. New information has been incorporated into Section 2 on population exposure assessment, including information on fish consumption surveys and consumption patterns of various fisher groups, and dose modification due to food preparation and cooking procedures. Additional information on risk characterization has also been added.

Section 3 of this document presents the information needed to calculate or modify the consumption limit tables provided for the 25 target analytes in Section 4. The reader is guided through calculation of risk-based consumption limits for carcinogenic and noncarcinogenic effects using the appropriate cancer slope factor (q_1^*)

Table 1-1. Target Analytes Recommended for Fish Sampling Programs [a]

Metals
- Arsenic (inorganic)
- Cadmium
- Mercury (methylmercury)
- Selenium
- Tributyltin

Organochlorine Pesticides
- Chlordane, total (*cis*- and *trans*-chlordane, *cis*- and *trans*-nonachlor, oxychlordane)
- DDT, total (2,4'-DDD, 4,4'-DDD, 2,4'-DDE, 4,4'-DDE, 2,4'-DDT, 4,4'-DDT)
- Dicofol
- Dieldrin
- Endosulfan (I and II)
- Endrin
- Heptachlor epoxide[b]
- Hexachlorobenzene
- Lindane (γ-hexachlorocyclohexane; γ-HCH)[c]
- Mirex[d]
- Toxaphene

Organophosphate Pesticides
- Chlorpyrifos
- Diazinon
- Disulfoton
- Ethion
- Terbufos

Chlorophenoxy Herbicides
- Oxyfluorfen

PAHs[e]

PCBs
- Total Aroclors[f]

Dioxins/furans[g,h]

PAHs = Polycyclic aromatic hydrocarbons.
PCBs = Polychlorinated biphenyls.

[a] The reader should note that carbophenothion was included on the original list of target analytes. Because the registrant did not support reregistration of this chemical, all registered uses were canceled after December 1989. For this reason and because of its use profile, carbophenothion was removed from the recommended list of target analytes.

[b] Heptachlor epoxide is not a pesticide but is a metabolite of the pesticide heptachlor.

[c] Also known as γ-benzene hexachloride (γ-BHC).

[d] Mirex should be regarded primarily as a regional target analyte in the southeast and Great Lakes States, unless historic tissue, sediment, or discharge data indicate the likelihood of its presence in other areas.

[e] It is recommended that tissue samples be analyzed for benzo[*a*]pyrene, benz[*a*]anthracene, benzo[*b*]fluoranthene, benzo[*k*]fluoranthene, chrysene, dibenz[*a,h*]anthracene, and indeno*[1,2,3-cd*]pyrene, and that the order-of-magnitude relative potencies given for these PAHs in the EPA provisional guidance for quantitative risk assessment of PAHs (U.S. EPA, 1993d) be used to calculate a potency equivalency concentration (PEC) for each sample (see Section 5 of Volume 1). At this time, EPA's recommendation for risk assessment of PAHs (U.S. EPA, 1993d) is considered provisional because quantitative risk assessment data are not available for all PAHs. This approach is under Agency review and will be evaluated as new health effects benchmark values are developed. Therefore, the method provided in this guidance document is subject to change pending results of the Agency's reevaluation.

[f] Analysis of total PCBs, as the sum of Aroclor equivalents, is recommended because of the lack of adequate toxicologic data to develop consumption limits for individual PCB congeners (see Section 5). However, because of the wide range of toxicities among different PCB congeners and the effects of metabolism and degradation on Aroclor composition in the environment, congener analysis is deemed to be a more scientifically sound and accurate method for determining total PCB concentrations.

[g] Note: The EPA Office of Research and Development is currently reassessing the human health effects of dioxins/furans.

[h] It is recommended that the 2,3,7,8-substituted tetra- through octa-chlorinated dibenzo-p-dioxins (PCDDs) and dibenzofurans (PCDFs) be determined and a toxicity-weighted total concentration calculated for each sample (Barnes and Bellin, 1989; U.S. EPA, 1987b) (see Section 5 of Volume 1). If resources are limited, 2,3,7,8-TCDD and 2,3,7,8-TCDF should be determined at a minimum.

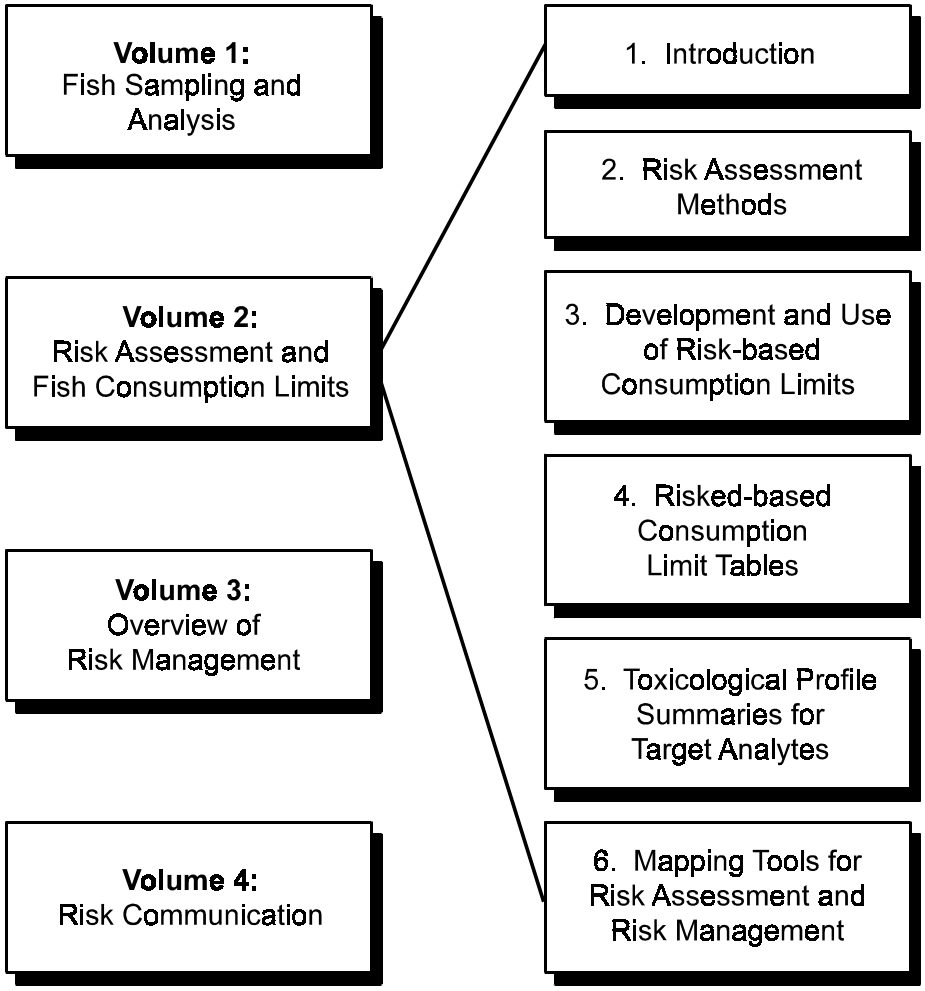

Figure 1-1. Series Summary: Guidance for Assessing Chemical Contamination Data for Use in Fish Advisories.

and reference dose (RfD). Information is also presented on calculation of consumption limits for developmental effects in women of reproductive age and young children. The reader is shown how selection of various input parameters such as the maximum acceptable risk level, consumer body weight, meal size, and time-averaging period influence fish consumption limits for single species diets. In addition, information is provided on methods for calculating consumption limits for single-species diets with multiple contaminants and multiple-species diets contaminated with a single or multiple contaminants.

The monthly consumption limits for each of the 25 target analytes are provided in Section 4. The tables list a number of alternative consumption limits for each target

analyte, based on different meal sizes, fish tissue contaminant levels, risk levels, and toxicity endpoints. Specific consumption limits have been developed, and are presented separately, for young children and adults in the general population. In addition, consumption limits specifically targeted to women of reproductive age have been developed for methylmercury and PCBs based on new toxicological information. Consumption limit tables have been added for arsenic, PAHs, and tributyltin.

Section 5 presents a toxicological profile summary for each of the 25 target analytes. Each profile summary contains a discussion of the pharmacokinetics, acute toxicity, chronic toxicity, developmental toxicity, mutagenicity, carcinogenicity, populations with special susceptibilities, interactive effects of the target analytes with other chemical contaminants, and critical data gaps with respect to toxicity. The most current EPA risk values (cancer slope factors and chronic reference doses) from sources such as EPA's Integrated Risk Information System (IRIS) and the Office of Pesticide Programs are provided, with a discussion of supporting dose-response data. The toxicological profile summaries have been modified for methylmercury and PCBs and new profile summaries have been added for arsenic, PAHs, and tributyltin.

Section 6 has been added to provide readers with an overview of GIS mapping tools for use in risk assessment and risk management. Mapping can be used to display information germane to all aspects of fish advisory programs. Maps may focus on fish contaminant levels, waterbodies where fish advisories are in effect, sport and subsistence fishing locations, or consumption levels of target populations of fishers. The reader is shown how to access EPA websites on the Internet to obtain additional GIS datasets and coverages.

In keeping with current EPA recommendations, discussions of uncertainty and assumptions are included in each section of the document. Although information was sought from a variety of sources to provide the best available data concerning the development of fish consumption advisories, limited data exist for some critical parameters (e.g., toxicological properties of certain chemicals and susceptibilities of specific populations such as the elderly, children, and pregnant or nursing women). Although substantial toxicological information is available for all target analytes discussed in this document, readers are cautioned to always consider the methods and values presented in the context of the uncertainty inherent in the application of science to policies for safeguarding the general public from environmental hazards.

The focus of this document is primarily on the risk due to consumption of non-commercially caught fish and shellfish from freshwater, estuarine, and marine waters. This document provides guidance on the evaluation of the overall risk associated with multimedia exposure to chemical contaminants found in fish (e.g., exposure due to other food sources, consumer products, air, water, and soil). EPA recommends that a comprehensive risk assessment be considered for all confirmed fish contaminants, including an evaluation of all significant exposure pathways (e.g., inhalation, dermal, and oral exposures).

Risk assessment and risk management of contaminated fish are complex processes due to the many considerations involved in setting fish consumption advisories, including both the health risks and benefits of fish consumption, the roles of State and Federal agencies, and the potential impact of advisories on economic and societal factors. These topics are discussed in Volume 3 of this guidance series (*Overview of Risk Management*). The final volume in the series deals with how risk managers can best communicate the health risks and benefits of fish consumption to the general public as well as recreational and subsistence fishers. These topics are detailed in Volume 4 (*Risk Communication).*

1.3 SOURCES

Information from a wide range of government and academic sources was used in the development of this document. Current approaches developed by States, regional groups such as the Great Lakes Sport Fish Advisory Task Force, and Federal agencies including EPA and the U.S. Food and Drug Administration (FDA) were reviewed. Section 7 contains a complete listing of literature sources cited in this document. Additional sources of information on risk assessment methods and issues specifically related to fish risk assessment may be obtained from the documents listed in Appendix A. These documents and scientific papers cover a range of topics, from general risk assessment methods, to chemical-specific toxicological data, to identification of chemical contaminant pathways.

In addition, to review the first edition of this document, EPA assembled an Expert Review Group consisting of officials from several EPA offices, FDA, regional groups, and the following States: California, Florida, Michigan, Delaware, Illinois, Minnesota, Missouri, North Dakota, New Jersey, and Wisconsin. A list of the experts and their affiliations is provided in the acknowledgments at the beginning of this document. The Expert Review Group contributed significant technical information and guidance in the development of the first edition of this document. Written recommendations made by the experts were incorporated into the final document. Some members were also consulted further on specific issues related to their expertise. In a second round of reviews, this document was circulated to all States, several Native American Tribes, and various Federal agencies for comment, and additional modifications were made. Participation in the review process does not imply concurrence by these individuals with all concepts and methods described in this document. The Expert Review Group did not review the current edition of the document because the basic risk assessment procedures had already been approved. This second edition was issued primarily to update new toxicological information for several analytes, to incorporate existing supplemental information into the body of the document, and to reformat the previous edition.